UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/738,540	12/14/2000	Wyne Pun Lee	P1795R1	2012

9157 7590 02/08/2002

GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER
HADDAD, MAHER M

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/738,540	LEE ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: Fax Transmission- Restriction Election.

DETAILED ACTION

Restriction Requirement

1. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. The following is noted:
A) Restriction is based on the claims as currently recited, however, it is noted that page 15, paragraph 2 of the specification discloses LFA-1 antagonist as small molecule, peptide, protein, immunoadhesin, an anti-LFA-1 antibody, or fragment thereof. Small molecules, peptides, proteins, immunoadhesins, and antibodies differ with respect to their structure, one of ordinary skilled in the art would not envision one in view of the other. If these additional LFA-1 antagonists are intended or claimed, they will be subject to further restriction. The Examiner noted that these molecules do not share a substantial structural feature essential to a common utility because their structures and mode of action are different.

B) Restriction is based on the claims as currently recited. However, page 16, paragraph 2 of the specification discloses TNF-α antagonist as ENBREL, Remicade, anti-TNFα, CDP-870, CDP 571, PEGylated soluble TNF-α recepor1, TBP-1, PASSTNF-alpha, AGT-1, TENEFUSE, CytoTAb, TACE, small molecule TNF mRNA synthesis inhibitor, PEGylated p75 TNFR Fc mutein, and TNF-α antisense inhibitor. If these additional TNF-α antagonists are intended or claimed, they will be subject to further restriction. The Examiner noted that these molecules do not share a substantial structural feature essential to a common utility because their structures and mode of action are different.

C) It is noted that the instant specification discloses diseases or disorders as TNFα-method or LFA-1 method, however given the overlap among the disclosed diseases or disorders, and the combination therapy, the claims are set forth as they read on "TNFα or LFA-1 method" mediated disorders or diseases.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-9, drawn to a method of treating a TNF-α or LFA-1 mediated disorder such as autoimmune pathologies comprising administering an anti-LFA-1 antibody and TNFα binding fusion protein, classified in Class 424, subclass 130.1 and 178.1.

II. Claims 1-9, drawn to a method of treating a TNF-α or LFA-1 mediated disorder such as infectious diseases comprising administering an anti-LFA-1 antibody and TNFα binding fusion protein, classified in Class 424, subclass 130.1 and 178.1.

III. Claims 1-9, drawn to a method of treating a TNF-α mediated disorder such as inflammatory disease comprising administering an anti-LFA-1 antibody and TNFα binding fusion protein, classified in Class 424, subclass 130.1 and 178.1.

IV. Claims 1-9, drawn to a method of treating a TNF-α mediated disorder such as neurodegenerative diseases comprising administering an anti-LFA-1 antibody and TNFα binding fusion protein, classified in Class 424, subclass 130.1 and 178.1.

V. Claims 1-9, drawn to a method of treating an LFA-1 mediated disorder such as cancer comprising administering an anti-LFA-1 antibody and TNFα binding fusion protein, classified in Class 424, subclass 130.1 and 178.1..

VI. Claims 1-9, drawn to a method of treating an LFA-1 mediated disorder such as organ transplantations comprising administering an anti-LFA-1 antibody and TNFα binding fusion protein, classified in Class 424, subclass 130.1 and 178.1.

VII. Claims 10-16, drawn to composition, comprising an anti-CD11a antibody and a TNFα fusion protein, classified in Class 514, subclass 8.

4. Groups I-VI are different methods. Each method differs with respect to ingredients employed; therefore, each method is patentably distinct.

5. Groups VII and I-VII are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group VIII can be used in screening proteins of invention I-VII, in addition to the methods of treating recited.

6. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

7. This application contains claims directed to the following patentably distinct species of the claimed Inventions I -VII: wherein the LFA-1 antibody against:

A) CD11a,
B) CD18, or
C) both CD11a and CD18.

These species are distinct because their structures and modes of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

8. This application contains claims directed to the following patentably distinct species of the claimed Invention I: wherein the autoimmune pathology is:

A) systemic lupus erythematosus rheumatoid arthritis,
B) thyroidosis,
C) graft versus host disease,
D) scleroderma,
E) diabetes mellitus, or
F) Graves' disease.
G) others, recited in the specification page 25-27, lines 1-40, lines1-40, and lines 1-17, respectively.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

9. This application contains claims directed to the following patentably distinct species of the claimed Invention II: wherein the infectious disease is:

A) sepsis syndrome,
B) cachexia,
C) HIV,
D) tuberculosis,
E) malaria, or
F) others, recited in the specification page 24, lines 19-21 and page 27, lines 21-29.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

10. This application contains claims directed to the following patentably distinct species of the claimed Invention III : wherein the inflammatory disease is:

A) sarcoidosis,
B) chronic inflammatory bowel disease,
C) ulcerative colitis, or
D) others, recited in the specification (page 24, lines 22-25).

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

11. This application contains claims directed to the following patentably distinct species of the claimed Invention IV: wherein the neurodegenerative disease is:

A) demyelinating diseases,
B) extrapyramidal and cerebellar disorders,
C) disorders of basal ganglia, or
D) others, recited in the specification on page 24, lines 25-39.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

12. This application contains claims directed to the following patentably distinct species of the claimed Invention V: wherein the cancer disease is:

A) malignant melanoma,
B) myeloma,
C) ovarian cancer,
D) breast cancer,
E) gastrointestinal tumors,
F) kidney/blader tumor,
G) Hodgkin's disease,
H) pancreatic carcinoma,
I) liver cell carcinoma, or
J) acute lymphoblastic leukemia.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

13. This application contains claims directed to the following patentably distinct species of the claimed Invention VI: wherein the organ transplantation disease is:

A) liver transplantation,
B) heart transplantion, or
C) kidney transplantation.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

14. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

15. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (703) 306-3472. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
January 28, 2002

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
2/7/02